

**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

## IN RE APPLICATION OF:

Allen, *et al.*

APPLICATION NO.: Not yet Assigned

FILED: Concurrently Herewith

FOR: **THERAPEUTIC LIPOSOME COMPOSITION  
AND METHOD OF PREPARATION**

EXAMINER: Unassigned

ART UNIT: Unassigned

**Information Disclosure Statement Within Three Months of  
Application Filing or Before First Action – 37 C.F.R. § 1.97(b)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

1. Timing of Submission

This information disclosure is being filed within three months of the filing date of this application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever occurs last (37 C.F.R. § 1.97(b)). The references listed on the enclosed Form PTO-1449 (modified) may be material to the examination of this application; the Examiner is requested to make them of record in the application.

2. Cited Information

☒ Copies of the following references are enclosed:

☒ Cite Nos.: 26, 31

☒ Copies of the following references can be found in parent U.S. Application No. 08/949,046:

☒ Cite Nos.: 1-5; 18, 21, 24, 27

☒ Copies of the following references can be found in parent U.S. Application No. 09/138, 480:

☒ Cite Nos.: 22, 25, 28, 30

☒ Copies of the following references can be found in parent U.S. Application No. 09/517,224:

☒ Cite Nos.: 8-11, 13, 14, 17, 18, 19, 20

- ☒ Copies of the following references can be found in parent U.S. Application No. 09/876,707:
  - ☒ Cite Nos.: 6, 7, 12, 15, 16, 23, 29
- ☒ This application is being filed after June 30, 2003, therefore no copies of U.S. patents or published applications are required.

3. Effect of Information Disclosure Statement (37 C.F.R. § 1.97(h))

This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

4. Fee Payment

No fees are believed due because this Information Disclosure Statement is being filed before the mailing date of the first Office Action.

However, should the Commissioner determine that fees are due in order for this Information Disclosure Statement to be considered, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-2207.

5. Patent Term Adjustment (37 C.F.R. § 1.704(d))

- ☐ The undersigned states that each item of information submitted herewith was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this statement. 37 C.F.R. § 1.704(d).

Respectfully submitted,

Date: April 7, 2004

Judy M. Mohr  
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> Form PTO-1449 (Modified) (Use several sheets if necessary)	<b>COMPLETE IF KNOWN</b>	
	Application Number	Unassigned
	Filed	Concurrently Herewith
	First Named Inventor	Allen <i>et al.</i>
	Group Art Unit	Unassigned
	Examiner Name	Unassigned
	Atty Dkt No.	55325-8148.US08
Sheet 1 of 2		

U.S. PATENT DOCUMENTS						
Examiner Initials	Cite No.	U.S. Patent or Application		Name of Patentee or Inventor of Cited Document	Date of Publication or Filing Date of Cited Document	Pages, Columns, Lines, Where Relevant Figures Appear
		NUMBER	Kind Code (if known)			
	1	5,013,556		Woodle <i>et al.</i>	05/1991	
	2	5,370,993		Tarnowski <i>et al.</i>	12/1994	
	3	5,395,619		Zalipsky	03/1995	
	4	5,534,241		Torchilin	7/96	
	5	5,620,689		Allen <i>et al.</i>	04/1997	
	6	5,631,018		Zalipsky	05/1997	
	7	5,932,462		Harri	8/99	

FOREIGN PATENT DOCUMENTS								
Examiner Initial	Cite No.	Foreign Patent or Application			Name of Patentee or Applicant of Cited Document	Date of Publication or Filing Date of Cited Document	Pages, Columns, Lines, Where Relevant Figures Appear	T
		Office	NUMBER	Kind Code (if known)				
	8	EP	354 855	A2	Hiroshi <i>et al.</i>	02/1990		
	9	EP	526 700	A2	Hosokawa <i>et al.</i>	02/1993		
	10	JP	7173079		Hayashi <i>et al.</i>	07/1995		
	11	PCT	WO 91/05545		Redemann <i>et al.</i>	05/1991		
	12	PCT	WO 94/21281		Martin, <i>et al.</i>	09/1994		

OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.	T
	13	Blumberg <i>et al.</i> , <i>J. Gen. Virol.</i> <b>66</b> :317-331, (1985).	
	14	Collins <i>et al.</i> , <i>Proc. Natl. Acad. Sci. USA</i> <b>81</b> :7683-7687, (1984).	
	15	Crystal, Ronald G., <i>Science</i> <b>270</b> :404-410, (1995).	
	16	DeFrees <i>et al.</i> , <i>J. Am. Chem. Soc.</i> , <b>118</b> :6101-6104, (1996).	
	17	Durell <i>et al.</i> , <i>Molecular Membrane Biology</i> <b>14</b> :97-112, (1997).	

EXAMINER	DATE CONSIDERED
*EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance <u>and</u> not considered. Include copy of this form with next communication to application(s).	

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	Group Art Unit	Unassigned
	Examiner Name	Unassigned
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Sheet 2 of 2		

18	Düzgünes <i>et al.</i> , <i>Biochemistry</i> <b>28</b> :9179-9184, (1989).	
19	Hsu <i>et al.</i> , <i>Proc. Natl. Acad. Sci. USA</i> <b>81</b> :7732-7736, (1984).	
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21	Kirpotin, D.B., <i>et al.</i> , <i>FEBS Letters</i> , <b>388</b> :115-118, (1996).	
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25	Park, J.W., <i>et al.</i> , <i>Proc. Natl. Acad. Sci. USA</i> <b>92</b> :1327-1331, (1995).	
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28	Uster <i>et al.</i> , <i>FEBS Letters</i> <b>386</b> :243-246, (1996).	
29	Zalipsky <i>et al.</i> , <i>Journal of Controlled Release</i> <b>39</b> :153-161, (1996).	
30	Zalipsky, <i>et al.</i> , <i>Bioconjugate Chem</i> , <b>8</b> :111-118, (1997).	
31	Zhu <i>et al.</i> , <i>Science</i> <b>261</b> :209-211, (1993).	

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